IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, *et al.* *ex rel.* CIMZNHCA, LLC, Plaintiff, v. UCB, INC.; RXC ACQUISITION COMPANY d/b/a RX CROSSROADS; OMNICARE, INC.; and CVS HEALTH CORPORATION, Defendants.	Case No. 3:17-CV-765-SMY-MAB

UNITED STATES' MOTION TO ALTER AND AMEND ORDER DENYING THE UNITED STATES' MOTION TO DISMISS THIS ACTION

The United States of America, pursuant to Rule 59(e) of the Federal Rules of Civil Procedure, respectfully requests that the Court reconsider its April 15, 2019 Memorandum and Order denying the government's motion to dismiss this enforcement action brought in the government's name and alter or amend the Order to grant the motion (Doc. 83).

I. Background

The Court's Memorandum and Order denying the United States' motion to dismiss summarizes the theories advanced by the Relator, CIMZNHCA, LLC (CIMZNHCA or the Relator), and the reasons the United States has identified for seeking to dismiss the action. *See* Doc. 83 at 1-2. At the hearing on the United States' motion to dismiss, the Court posed questions to counsel regarding the scope of the government's investigation, the numerical details underlying its cost-benefit analysis, and whether the government's motion was based on animus toward CIMZNHCA or its associates. *See* Doc. 81 at 26-54. Following the hearing, the United

States moved for leave to supplement and correct the record on these subjects (Doc. 78); however, the Court denied the motion (Doc. 79). The Court thereafter denied the United States' motion to dismiss in a written Memorandum and Order dated April 15, 2019 (Doc. 83).

II. Legal Standard

A motion for reconsideration of a district court order may be adjudicated under Rule 59(e) of the Federal Rules of Civil Procedure. *See, e.g., Mares v. Busby*, 34 F.3d 533, 535 (7th Cir. 1994). The motion may be granted if the movant identifies a mistake of fact or law, or presents newly discovered evidence that could not have been discovered previously. *Matter of Prince*, 85 F.3d 314 (7th Cir. 1996); *Deutsch v. Burlington N. R.R. Co.*, 983 F.2d 741 (7th Cir. 1993). Reconsideration is an appropriate vehicle to correct mistaken findings that are inconsistent with the facts. *See generally Cullum v. Davis*, No. 15-CV-00057-SMY-PMF, 2016 WL 6582401, at *1 (S.D. Ill. Nov. 7, 2016) (collecting cases).

III. Discussion

In denying the United States' motion to dismiss this action brought in its name, the Court misapplied the Ninth Circuit's decision in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998).[1] As explained more fully below, the Court erred in substituting its judgment for the government's in determining how the government should apply its limited resources, and in concluding that the government needed to conduct

[1] For the reasons given in its Memorandum of Law in Support of Motion to Dismiss, Doc. 64 at 9-12, the United States respectfully maintains that the more deferential standard adopted by the D.C. Circuit in *Swift v. United States*, 318 F.3d 250, 252 (2003), is the correct standard for evaluating a motion to dismiss under 31 U.S.C. § 3730(c)(2)(A). For purposes of the current motion, however, the United States will limit its discussion only to the Court's application of the *Sequoia Orange* standard to the facts of this case. However, the government preserves for appeal its arguments regarding the appropriate legal standard that should govern its motion to dismiss.

further investigation before seeking to dismiss this action to preserve those resources. The Court also erred in concluding that the government failed to conduct any "cost-benefit analysis," and failed to adequately consider the United States' legitimate policy interests in ensuring patients receive basic product support and instruction relating to their prescribed medications and its concern that the relator's allegations would chill these beneficial practices. Finally, the Court's observation that "one could reasonably conclude" the government's "true motivation is animus towards the relator" is manifestly inaccurate and flatly contradicted by substantial evidence, some of which the government did not have an opportunity to present to the Court during the hearing.

A. The Court Misapplied the *Sequoia Orange* Standard

In *Sequoia Orange*, the Ninth Circuit adopted a highly deferential standard for reviewing the government's requests to dismiss *qui tam* suits under 31 U.S.C. § 3730(c)(2)(A), explaining that "the decision to dismiss has been likened to a matter within the government's prosecutorial discretion in enforcing federal laws." 151 F.3d at 1143. The Ninth Circuit explained that this test is "[t]he same analysis [that] is applied to determine whether executive action violates substantive due process," *id.*, and emphasized that this standard "respect[s] the Executive Branch's prosecutorial authority by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself," *id.* at 1146.

Thus, under *Sequoia Orange*, a relator challenging the United States' decision to dismiss a *qui tam* action must show that the government's decision lacks *any* rational basis. And the examples cited by the court in *Sequoia Orange* make clear that this is an exceedingly deferential standard designed to cover only egregious government misconduct. *See, e.g.*, *Sequoia Orange*, 151 F.3d at 1146 (citing *United States v. Redondo-Lemos*, 955 F.2d 1296, 1299 (9th Cir. 1992)

("[I]t would offend common notions of justice to have [charging decisions] made on the basis of a dart throw, a coin toss or some other arbitrary or capricious process."), *overruled on other grounds by United States v. Armstrong*, 517 U.S. 456 (1996)). The United States' stated reasons for dismissal in this case stand in stark contrast to the very limited circumstances that the Ninth Circuit identified as justifying the extreme action of denying the government's broad authority to dismiss a *qui tam* action.

This deferential standard of review reflects the latitude given governmental decisions regarding enforcement actions. As the Supreme Court has explained, "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (collecting cases). The Supreme Court outlined the "many" reasons why such nonenforcement decisions are "general[ly] unsuitab[le] for judicial review." *Id.* Such decisions "often involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," and require the agency to assess "whether agency resources are best spent on this violation or another, … and, indeed, whether the agency has enough resources to undertake the action at all." *Id.* (noting that "[a]n agency generally cannot act against each technical violation of the statute it is charged with enforcing").

In this case, the United States has identified two rational bases furthered by dismissal: (1) the Relator's unsupported allegations do not justify the further expenditure of government resources; and (2) prosecuting this case would potentially undermine beneficial practices involving the provision of basic product support and instruction to patients. *See* Doc. 64 at 13-16. The Court erred in concluding that the government failed to conduct a "minimally adequate

investigation to support" these purposes, and further erred in concluding that the government's decision to dismiss was arbitrary and capricious. Doc. 83 at 6.

B. *Sequoia Orange* Does Not Allow the Court to Substitute Its View on the Amount of Investigation Required by the United States

Sequoia Orange held that a court's review of the government's motion to dismiss a *qui tam* action is governed by "[t]he same analysis [that] is applied to determine whether executive action violates substantive due process," 151 F.3d at 1139, and should require "no greater justification of the dismissal motion than is mandated by the Constitution itself," *id*. at 1146. This standard imposes no obligation on the government to engage in any particular degree of investigation before making a decision whether to pursue an enforcement action. To the contrary, the government is permitted to forgo even those enforcement actions it *knows* would prove meritorious, given the agency's prerogative – and need – to balance agency priorities and to choose which actions warrant the expenditure of its limited resources and which do not. *See Heckler*, 470 U.S. at 831-32.

As the Supreme Court has explained, factors like "the strength of the case, the prosecution's general deterrence value, the Government's enforcement priorities, and the case's relationship to the Government's overall enforcement plan are not readily susceptible to the kind of analysis the courts are competent to undertake." *Armstrong*, 517 U.S. at 465. Indeed, the very due process case that the Ninth Circuit invoked in *Sequoia Orange* recognized the problems with second-guessing the government's prosecutorial discretion. *See Redondo-Lemos*, 955 F.2d at 1299-99 (recognizing that "[i]t would raise serious separation of powers questions—as well as a host of virtually insurmountable practical problems—for the district court to inquire into and supervise the inner workings of the United States Attorney's Office"), cited in *Sequoia Orange*, 151 F.3d at 1146.

To the extent that the Court derived its full-investigation requirement from the legislative history referenced at the hearing on the government's motion, *see* Doc. 81 at 12, this was erroneous. In *Sequoia Orange*, after setting out its rational basis test, the Ninth Circuit stated that its standard for adjudicating Section 3730(c)(2)(A) motions "draws significant support from" a 1986 Senate Report. *See* 151 F.3d at 1145 (citing S. Rep. No. 99-345, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5291). The Ninth Circuit observed that, according to the Senate Report, "[a] hearing is appropriate 'if the relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government's decision was based on arbitrary or improper considerations.'" *Id.*[2]

This portion of *Sequoia Orange* does not suggest that the Ninth Circuit intended to modify the rational basis standard of review it had just set out. *See* 151 F.3d at 1145. Indeed, immediately before quoting this portion of the Senate Report, the Ninth Circuit noted that it was adopting the same analysis applied to substantive due process claims. *See id.* And immediately after quoting this portion of the Senate Report, the court noted the importance of respecting Executive Branch "decisions to dismiss qui tam suits in the exercise of its prosecutorial authority," and emphasized that it was demonstrating such respect "by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself." *Id.* at 1145-46.

[2] As the D.C. Circuit noted in *Swift*, the portion of the Senate Report quoted in *Sequoia Orange* "relates to an unenacted Senate version of the 1986 amendment." *Swift*, 318 F.3d at 253. That unenacted version discussed a relator's options after the government had intervened and "proceed[ed] with the action." *Id.* (quoting S. Rep. No. 99-345, at 42). The D.C. Circuit reasoned that "[t]he whole point here is that the government has not elected to proceed; it has elected to dismiss the case," and thus concluded that this portion of the Report has no bearing on Section 3730(c)(2)(A) as enacted. *Id.*

Thus, to the extent that the Court imported the factors the Senate Report referred to as possible justifications for a hearing into the standard for reviewing the dismissal motion itself, such reasoning ignores the nature and the limits of rational basis review. If a court could substitute its views for those of the government as to the strength of the case or the degree of governmental investigation required, it would result in the very sort of judicial entanglement in the Executive Branch's weighing of its enforcement priorities that the Supreme Court has made clear is impermissible. *See Armstrong*, 517 U.S. at 465; *Heckler*, 470 U.S. at 831-32. Moreover, it would lead to the illogical result that the government would be required to expend government resources before it could move to dismiss a *qui tam* action in order to preserve those very same resources. In sum, how the Executive Branch makes resource allocation determinations falls well outside rational basis review.

C. The Government Adequately Investigated this Case

Even if the United States were required to demonstrate that it conducted an adequate investigation, it clearly made that showing, and the Court's finding to the contrary ignores key facts. In determining that the United States failed to conduct a "minimally adequate investigation" of the Relator's *qui tam* complaint, the Court relied on two erroneous conclusions: (1) that the government reviewed the Relator's complaint and disclosure materials but "did not review any additional materials from the relator relevant to this case" and (2) that while the government undertook certain investigative steps "collectively" in conjunction with ten other virtually identical *qui tam* complaints filed by the Relator and its associates, its investigation was insufficient because it failed to duplicate those same investigative efforts for each case. Doc. 83 at 5-6.

First, the United States' investigation in this particular case consisted of more than simply reading the Complaint and disclosure materials. As noted in the United States' Memorandum of Law in Support of Its Motion to Dismiss, the Department of Justice "consulted with subject-matter experts at HHS-OIG about the relators' allegations and the applicability of regulatory safe harbors and government-issued industry guidance." Doc. 64 at 14. This included attorneys from both HHS-OIG's Administrative and Civil Remedies Branch and its Industry Guidance Branch who possess more than 90 years of combined experience managing and implementing the United States' policies and enforcement efforts relating to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS). At the hearing on the government's motion, counsel for the United States further noted examples of nine specific agency guidance documents that the government reviewed. Doc. 81 at 47:10-49:3.

Second, it is incorrect to suggest that beyond the Relator's complaint and initial disclosure materials the United States "did not review any additional materials from relator relevant to this case." Doc. 83 at 6. Upon receiving the Relator's complaint and initial disclosures, the United States carefully reviewed all this information, including over 300 pages of interview transcripts. The Court's decision incorrectly implies that the Relator had some additional information that the government failed to request and consider beyond this initial information. The record belies this presumption. At the hearing on the government's motion, counsel for the Relator conceded that, prior to declination, the assigned Assistant United States Attorney inquired whether the Relator had any additional information to provide, and the Relator's counsel responded that the Relator had no additional information. Doc. 81 at 24:24-25:11; *see also id.* at 24:1-3 (Relator's counsel confirming, "we did not provide any additional information in this case other than what was provided in the disclosure statement."); *id.* at 30:5-

14 (government counsel confirming that the United States "sought out" additional information from the Relator, but the Relator advised it had none). The United States should not be faulted for failing to consider information that the Relator never provided, much less information the Relator concedes did not exist. Moreover, as detailed below, before exercising its dismissal authority, the government gave the relators in all of the related *qui tam* cases, including CIMZNHCA, the Relator in this case, yet another opportunity to present to the government any information that supported the allegations that the government was considering dismissing and to explain why the government should not exercise that authority. Notably, CIMZNHCA provided no additional information or evidence about this case at that time.

Finally, it was entirely appropriate for the United States to coordinate certain investigative steps across the various *qui tam* actions filed by the Relator and its affiliates operating under the NHCA Group umbrella, since the *qui tam* complaints plead substantially the same allegations (sometimes copied word-for-word) and implicate the same legal issues, the same industry practices, and a number of the same defendants. Indeed, the Relator's parent organization, NHCA Group, through its counsel, *requested* that the Department of Justice coordinate its efforts and positions across the various cases it had filed involving substantially similar theories. *See* Declaration of Nicholas C. Perros, attached hereto as Exhibit 1, at ¶ 3. Furthermore, it was reasonable to discuss the legal issues and policy interests with agency subject-matter experts across all cases since they present the same legal issues and policy considerations. Similarly, when seeking an estimate of the costs associated with collecting Medicare data, it was reasonable to inquire about such costs for all pending cases. That certain efforts were undertaken "collectively" does not diminish the fact that the United States adequately investigated the allegations in this particular case, which span a mere four pages in

the Complaint. *See* Doc. 2 at 24-28. This is especially true considering that, contrary to the representation made by the Relator's counsel to the Court at the hearing on the United States' motion to dismiss, *see* Doc. 81 at 24:4-10, there is substantial overlap among defendants, with at least seven defendants who are named in multiple *qui tam* actions premised on the same business practices and same legal theories. That several defendants were investigated multiple times for the same practices is particularly relevant in this case, where CIMZNHCA has named one of the same defendants (RX Crossroads) that its affiliate, SMSPF, sued in the Eastern District of Pennsylvania, where the court concluded the allegations were "fully investigated" by the government *See United States ex rel. SMSPF, LLC, et al. v. EMD Serono, Inc., et al.*, No. 16-5594, 2019 WL 1468934, *5 (E.D. Pa. April 3, 2019).

D. The United States Analyzed the Costs and Benefits of Further Litigation

The Court further erred in concluding that the United States failed to undertake a "cost-benefit analysis" that considered "the costs it would likely incur versus the potential recovery that would flow to the Government if this case were to proceed." Doc. 83 at 6. As an initial matter, where, as here, the government has determined that the relator failed to provide any support for its allegations, it is not clear how the government is supposed to assess the case's "potential recovery." In *Sequoia Orange*, the Ninth Circuit explicitly recognized as a valid basis to dismiss the government's proffered rationale that "the government would continue to incur enormous internal staff costs" and did not require any specific accounting of those costs. *Sequoia Orange*, 151 F.3d at 1146. Numerous courts have since accepted preservation of government resources as a valid government interest rationally related to dismissal under section 3730(c)(2)(A) *without* requiring the government to furnish specific calculations, estimates, or

dollar figures.[3] *See, e.g., United States ex rel. SMSPF, LLC*, 2019 WL 1468934; *United States ex rel. Sibley v. Delta Regional Med. Ctr.*, No. 4:17-cv-00053, 2019 WL 1305069 (N.D. Miss., March 21, 2019); *United States ex rel. Davis v. Hennepin County*, No. 18-cv-01551 (ECT/HB), 2019 WL 608848, at *7 (D. Minn. Feb. 13, 2019); *United States ex rel. Toomer v. TerraPower, et al.*, 4:16-cv-00226, 2018 WL 4934070 (D. Idaho Oct. 10, 2018); *United States ex rel. Stovall v. Webster Univ.*, No. 3:15-CV-03530-DCC, 2018 WL 3756888, at *3 (D. S.C. Aug. 8, 2018); *United States ex rel. Maldonado v. Ball Homes, LLC*, 5:17-cv-379, 2018 WL 3213614 (E.D. Ky. June 29, 2018); *United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17, 2015 WL 1499519, at *5 (E.D. Ky. Apr. 1, 2015); *United States ex rel. Nasuti v. Savage Farms, Inc.*, 2014 WL 1327015 (D. Mass. Mar. 27, 2014), aff'd, 2015 WL 9598315 (1st Cir. 2015). Nonetheless, the United States properly considered the costs and benefits of further litigation, including, among other things, the following:

- The resolution of another companion *qui tam* action involving the NHCA Group (the Relator's parent company) that was previously brought against Novo Nordisk and other defendants making similar kickback allegations implicating similar industry practices relating to nurse educators. *See U.S. ex rel. Doe v. Novo Nordisk, et al.*, No. 1:17-cv 791 (D.D.C.). Following the government's declination, the NHCA Group-affiliated relators settled their allegations for $350,000. *See* Exhibit 2, Declaration of Colin M. Huntley (Huntley Decl.) at ¶ 23.

[3] As a practical matter, requiring the United States to attempt to calculate the costs of enforcement actions it has determined lack merit could lead to highly imprecise results, inasmuch as the costs of meritless enforcement actions are not limited to the government's expenditures but may be far-reaching and difficult to quantify, including, for example, burdens imposed on third-party healthcare professionals and federal healthcare program beneficiaries.

- Cost estimates provided by personnel from the Centers for Medicare and Medicaid Services relating to the cost of collecting and producing the relevant Medicare Part D claims data for the NHCA Group cases then pending.
- Proposed discovery requests propounded by defendants in companion NHCA Group cases involving substantially the same allegations and anticipated defenses.
- The discovery orders proposed by the Relator's NHCA Group affiliates in two of its cases filed in the Eastern District of Texas, which involve substantially the same allegations and legal issues that are presented in this case. These discovery orders include a total of 700 hundred hours of deposition time for "government witnesses." *See* Doc. 81 at 37:11-38:9.
- The third-party discovery requests that have been served on the United States in other declined *qui tam* actions involving other relators, including actions against pharmaceutical and life sciences companies involving AKS allegations.
- The costs and resources routinely incurred in other declined cases involving AKS allegations, including drafting statements of interest relating to the AKS, its statutory exceptions and regulatory safe harbors, and HHS-OIG guidance.

Although the Relator's counsel indicated at the hearing that the Relator anticipates that most of its discovery would be "directed at the defendants" and perhaps other healthcare providers, Doc. 81 at 54:8-55:19, this fails to account for discovery propounded by defendants. If this case were to go forward, the defendants will almost certainly seek substantial discovery from the United States, and Relator's suggestion to the contrary is simply not credible.

Finally, the United States also considered human capital and opportunity costs stemming from the need to divert resources away from more meritorious matters. Given that well over 600

new *qui tam* actions are filed every year, this is a significant practical consideration that the United States properly evaluated. Regardless of whether the Relator or the Court believe that the Relator's allegations warrant the expenditure of additional taxpayer funds or disagree with the United States' assessments of anticipated costs and burdens, this does not render the government's view arbitrary and capricious. *See United States ex rel. Nicholson v. Spigelman*, No. 10-cv-3361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (rejecting relator's claim that the government "seriously underestimated the financial upside of the litigation," explaining, "[t]he government's cost-benefit analysis may be sound or it may be short-sighted, but it cannot be deemed arbitrary and capricious.").

E. The Government has Proffered a Legitimate Policy Interest that is Rationally Related to Dismissal

The Court also erred in its conclusion that the United States does not have a valid policy interest that is rationally related to dismissal. *See* Doc. 83 at 6. As the government explained in its Memorandum of Law in Support of its Motion to Dismiss, the Relator is challenging "common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal healthcare programs and their beneficiaries." Doc. 64 at 16. As the United States further explained, the government has an interest in ensuring that patients have access to basic product support relating to their prescribed medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medicine. *Id.* at 15. Because the government spends vast sums on medications, including Cimzia, it stands to reason that the government has an interest in not unduly discouraging programs that may help patients take the medications properly.

The Court erred in rejecting these significant policy interests as "curious at best." Doc. 83 at 6. It is neither improper nor unusual for government agencies such as HHS-OIG to assess

the public policy implications of potential enforcement actions premised on statutes such as the AKS. HHS-OIG's work in this area is reflected in scores of publicly-available documents, including industry guidance and advisory opinions referenced at the hearing on the government's motion to dismiss in this case. *See* Doc. 81 at 47:13-48:22. HHS-OIG routinely considers potential programmatic benefits arising from conduct that promotes "access to care" for beneficiaries, and the agency has publicly underscored this policy interest numerous times over the past several years.

For example, in 2016, after two years of reviewing public comments, HHS-OIG finalized a new exception focused on "access to care" for the Beneficiary Inducement Law, which is similar in many respects to the AKS and prohibits providing certain remuneration to patients enrolled in Medicare and Medicaid. *See Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, 81 FR 88368-01, 2016 WL 7103282 (Dec. 7, 2016), cited by government counsel at Doc. 81, 48:18-22. In general terms, the "access to care" exception is intended to allow certain items or services to be provided directly to patients in cases where the programmatic risks are low and there is a sufficient benefit to patients or the healthcare program. 81 FR at *88368. OIG has publicly stated that its objective is to "ensure that [it] protects low-risk, beneficial arrangements." *Id.* at *88370. OIG has applied the same "access to care" policy considerations relevant to the Beneficiary Inducement Law to its analyses under the AKS.[4] In light of the agency's stated policy objectives, it is apparent that this case

[4] *See, e.g.*, OIG Advisory Opinion No. 17-01, 2017 WL 1075198 (Dep't of Health and Human Servs. Mar. 3, 2017). Although drug manufacturers may not face liability under the Beneficiary Inducement Law, policy considerations applicable to the law also apply to the case at hand.

implicates a substantial policy interest insofar as the allegations center on the provision of product support and educational information to patients after they have been prescribed medications. The government's policy and enforcement assessment in this case is exactly the sort of "complicated balancing" of factors "peculiarly within [the agency's] expertise" that the Supreme Court contemplated in *Heckler*.[5]

Finally, the policy interest discussed above is rationally related to dismissal. As the Tenth Circuit explained when following *Sequoia Orange*, "there need not be a tight fitting relationship" between the government's stated reason and dismissal; rather, "it is enough that there are plausible, or arguable, reasons supporting the agency decision." *Ridenour*, 397 F.3d at 930 (citations omitted). Stated another way, "even when the legitimate interest articulated by the Government is only incidentally advanced, the rational relationship test has been satisfied." *United States ex rel. Fay v. Northrop Grumman Corp., et al.*, No. 06-cv-00581, 2008 U.S. Dist. Lexis 24481, at *19 (D. Colo. Mar. 27, 2008) (quoting *United States ex rel. Ridenour v. Kaiser-Hill Co.*, 174 F. Supp. 1147, 1155 (D. Colo. 2001), *aff'd*, *Ridenour*, 397 F.3d 925). But even if a closer nexus were required, it would be satisfied in this case. Continued litigation by the Relator of the very practices that the Government believes to be beneficial could have a profound

[5] The Court's Memorandum and Order indicates that the United States "acknowledged" that the relator is asserting "a classic violation of the AKS." Doc. 83 at 6. There is no citation provided for this purported acknowledgement. Neither the United States' brief nor the transcript of the hearing reflect any such acknowledgement. It appears that the Court may be referring to a colloquy that appears at 44:9-46:11 of the transcript, Doc. 81. However, in this colloquy, the United States acknowledged that protecting the integrity of physician decision-making is an important policy underlying the AKS, not that the Relator has asserted a "classic violation" of the AKS. To be clear, Relator has <u>not</u> asserted a "classic" AKS theory when it alleges that truthful, non-misleading product support and education provided directly to patients at their homes or over the telephone constitutes unlawful in-kind remuneration to their prescribing physicians. This explains why the Relator and its affiliates have not cited a single FCA case that has succeeded on this novel theory of liability.

chilling effect on those practices. This constitutes a tight-fitting rational relationship by any measure.

F. The Government's Motion to Dismiss is Not Based on Animus, and the Government Has Treated the Relator and Its Affiliates Fairly

The Court also erred in determining that "one could reasonably conclude … the Government's true motivation is animus towards the relator," Doc. 83 at 7. While the Court appears to have reached this conclusion based on the number of pages in the United States' brief discussing the Relator's business model and an isolated excerpt from the hearing, the Court's conclusion is mistaken for three primary reasons.

First, the United States' dealings with NHCA Group and its associates belie any suggestion of animus. Before filing its motion to dismiss in this action, the United States spent considerable time over the course of ten weeks discussing the NHCA Group cases with counsel for the *qui tam* investors and counsel for the affiliated corporate relators in each case, including counsel for CIMZNHCA. *See* Huntley Decl. at ¶¶ 2-22. At the request of NHCA Group, these discussions related to all of its cases and included: (1) a 90-minute meeting on October 18, 2018, in which the NHCA Group relators were represented by 16 attorneys from nine different law firms, including attorneys representing CIMZNHCA in this case; (2) a 60-minute telephone conference on November 6, 2018, in which NHCA Group counsel had an opportunity to discuss all of the cases with the Assistant Attorney General for the Civil Division and a Deputy Associate Attorney General, among others; and (3) supplemental information provided by NHCA Group, at the invitation of the Department, on October 18, November 8, and November 30, along with correspondence sent by NHCA Group to the Department on October 26, October 29, October 31, November 28, November 29, December 11, and December 13. *Id.* The United States' evaluation of this case was based, in part, on these ten weeks of discussion and the

supplemental information provided by the Relator and its affiliates (though, as noted above, during the course of these discussions the government received no additional information or evidence from the Relator in this case). On several occasions, NHCA Group counsel requested that the United States delay filing its motions to dismiss to allow for further discussion and evaluation of the various matters, including this one, and the government accommodated these requests. *Id.* at ¶¶ 4, 6, 12, 16.

These facts demonstrate that the government has treated the Relator and its associates fairly – a fact reflected in the parties' contemporaneous communications. To take just one example, in correspondence dated November 13, 2018, NHCA Group counsel stated, "We appreciate that significant policy issues are in play, and very much appreciate your commitment to consider our position fairly." *Id*. at ¶ 17. The Relator and its associates' contemporaneous recognition of fair treatment, and the government's actions establishing the same, are far more probative than the Relator's unsubstantiated *post hoc* claims of animus.

Second, the corporate structure of Venari Partners LLC and its investigative methods are relevant for several reasons, including (a) explaining how the same allegations came to be copied across 11 *qui tam* complaints filed across six states; (b) informing the reliability and weight of the allegations; and (c) demonstrating that neither the corporate Relator entity (CIMZNHCA, LLC) nor its investors has any personal knowledge or first-hand information relating to their allegations. Pointing these facts out is not a matter of animosity; it is directly relevant to the government's assessment of the likely merit – or lack thereof – of the Relator's allegations. Nor is the government "deriding the relator's business model" when it notes concern that the Relator's investigative methods in this case involved deceptive conduct. Indeed, another federal court found similarly deceptive conduct violated the rules of professional conduct and sanctioned

the violation with an order of dismissal. *See United States ex rel. Leysock v. Forest Labs., et al.*, No. 1:12-cv-11354-FDS, 2017 WL 1591833 (D. Mass. April 28, 2017).

Third, the excerpted question and answer from the hearing do not evidence animus, particularly when one considers the complete response provided by government counsel. In the text immediately following the excerpted answer, government counsel explained that it is appropriate to consider how relators "conduct themselves" because the United States has to "think ahead to actual proof problems," which necessarily includes whether there is "something about the Relator that would affect their credibility." *See* Doc. 81 at 49:22-50:3. This exchange does not reflect animus. And it is hardly controversial that the Department assesses the credibility of relators as it does with any other witness. Importantly, after the excerpt cited by the Court, government counsel explicitly affirmed that the "Government's opinion as to the Relator" was not the basis for the motion to dismiss. *See* Doc. 79 at 51:2-18.

The Court should bear in mind that NHCA Group has filed numerous other *qui tam* actions over the past several years, many of which involve entirely different sectors of the healthcare industry and different legal theories. The United States has dutifully investigated each and every case and has allowed many to proceed following declination. *See, e.g., United States ex rel. Doe v. Novo Nordisk, Inc.*, et al., No. 17-cv-791 (D.D.C.); *United States ex rel. Doe v Lincare Holdings Inc*., No. 5:15-CV-19 DCB-MTP (S.D. Miss.); *United States ex rel. Doe, et al. v INSYS Therapeutics Inc., et al*. No. 14-CV-3488 (C.D. Cal.); *United States ex rel. Stop Louisiana Healthcare Fraud LLC v Champion Mgt. LLC et al*., No. 2:14-CV-159 (E.D. La.); *United States ex rel. Stop Illinois Marketing Fraud LLC v Addus HomeCare Corp., et al.*, No. 13-CV-9059 (N.D. Ill.); *United States ex rel. Stop Illinois Health Care Fraud LLC v Sayeed, et al*. No. 12-CV-9306 (N.D. Ill.). When considering the full history of the United States'

interactions with NHCA Group, the most reasonable inference is that the United States' decision to dismiss the allegations in this case, and its companion cases, is based on its assessment of the particular allegations now being advanced, rather than any antipathy toward the organization itself.

IV. Conclusion

The United States respectfully moves the Court to reconsider its denial of the United States' Motion to Dismiss (Doc. 83).

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

STEVEN D. WEINHOEFT
United States Attorney

Dated: April 29, 2019

By: */s/ Nathan D. Stump*

NATHAN D. STUMP
Assistant United States Attorney
9 Executive Drive
Fairview Heights, IL 62208
Tel: (618) 628-3700
Fax: (618) 622-3810
Nathan.Stump@usdoj.gov

MICHAEL D. GRANSTON
PATRICIA L. HANOWER
COLIN M. HUNTLEY
ALBERT P. MAYER
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 353-1291
Fax: (202) 307-3852
albert.p.mayer@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of April, 2019, I caused this document, filed through the ECF system, to be sent electronically to the registered participants as identified on the Notice of Electronic Filing ("NEF"), and that paper copies will be sent to those indicated as non-registered participants.

Dated: April 29, 2019

By: */s/ Nathan D. Stump*
NATHAN D. STUMP
Assistant United States Attorney